County of Erie

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COUNTY EXECUTIVE

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COMMISSIONER OF HEALTH

TO: All E.M.S. Providers

FROM: John Adolf, Deputy Commissioner / E.M.S.
Erie County Division of Emergency Medical Services

DATE: April 1, 2013

SUBJECT: Hospira 0.9% Sodium Chloride Voluntary Recall

FOR IMMEDIATE RELEASE - March 29, 2013 - Hospira, Inc. (NYSE: HSP), announced today it is initiating a voluntary nationwide user-level recall of one lot of 0.9% Sodium Chloride Injection, USP, 1000 mL, Flexible Container, **NDC 0409-7983-09.** This action is due to one confirmed customer report where brass particulate was identified in the primary container in the form of several small grey/brown particles. To date, Hospira has not received reports of any adverse events associated with this issue for this lot, and has not identified any quality issues with retention samples for this lot. This recall is being conducted as a precautionary measure.

The brass particulate was identified as containing copper, zinc and lead. If the particulate is undetected, there is a potential for delay in therapy, or if administered, solution containing brass particulate may result in occlusion of small blood vessels. In a worst-case scenario, copper toxicity may potentially result in hemolysis and liver toxicity, including hepatic necrosis which may be fatal.

The product is used as a source of water and electrolytes and is packaged in a 1000 mL flexible container, **lot number 25-037-JT (the lot number may be followed by a -01 or -90)**, with an expiration date of January 1, 2015. The affected lot was distributed nationwide between January 2013 and March 2013 to wholesalers/distributors, hospitals and pharmacies.

Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-888-480-2853 between the hours of 8am to 5pm EST, Monday through Friday, to arrange for the return of the product. Replacement product from other lots is available.

Hospira is investigating to determine the root cause.

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (8am-5pm CT, M-F) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 or medcom@hospira.com (Available 24 hours a day/7 days per week)	Medical inquiries

Any adverse reactions or quality problems experienced with the use of this product may be reported to the U.S. Food and Drug Administration's (FDA) MedWatch Adverse Events Program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular mail: use postage-paid, pre-addressed Form FDA3500 available at www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Cc Commissioner Burstein
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